510(k) SUMMARY

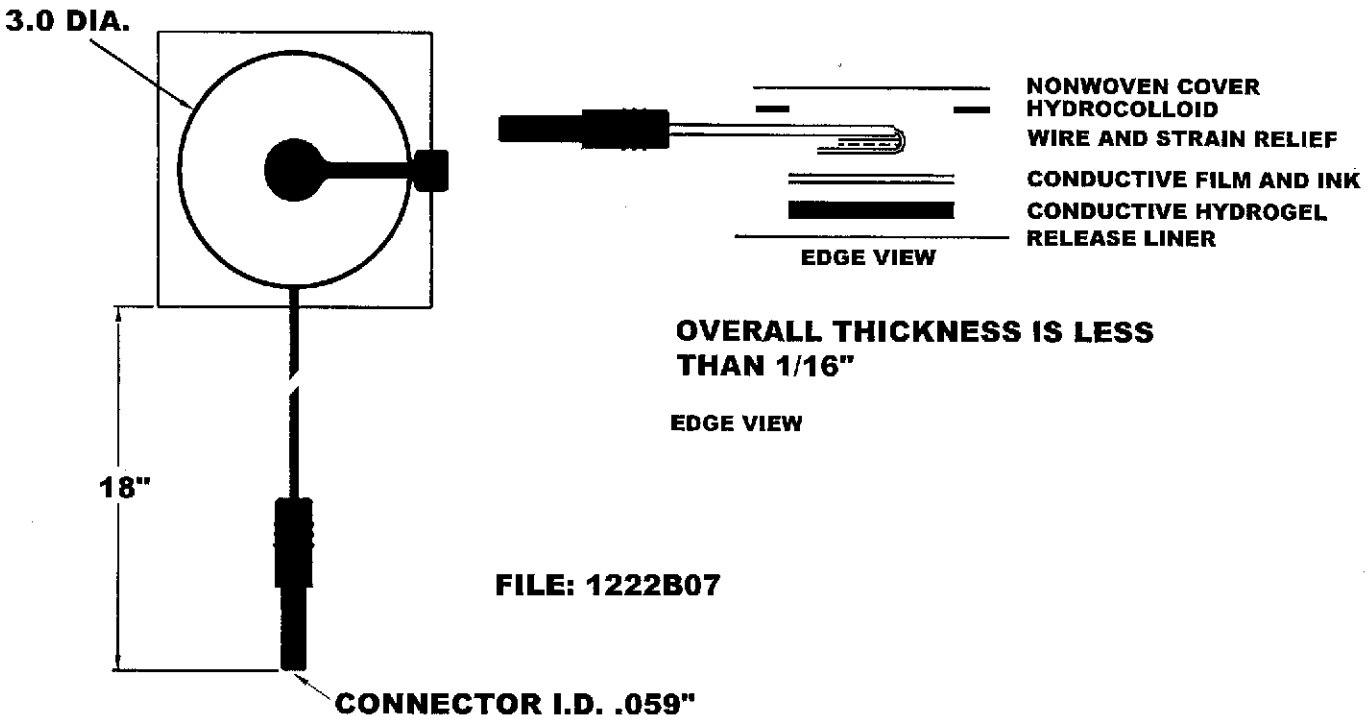
APR 24 2008

K072799

Statement:	This summary of 510(k) substantial equivalence is being submitted in accordance with the requirements of 21 CFR 807.92.
Submitter's Identification:	Vision Quest Industries, Inc. 18011 Mitchell South Irvine, CA 92614 Contact Person: Jaime Pulley, V.P. of Quality Assurance/ Regulatory Affairs Phone: (760) 477-8201 Fax: (760) 734-1577
Date Summary Prepared:	September 29, 2007
Name of Device:	Proprietary Name: Target Sterile Electrode Common Name: Cutaneous Electrode
Classification Name:	(GXY)
Predicate Device Name:	Surgi-Stim Sterile Electrodes 510(k) # K041953 ConMed Corporation 525 French Rd. Utica, NY 13502

Description and Intended use:
The Target Sterile Electrodes are intended for use as a single patient, sterile, disposable, adhesive conductive interface between the patient's skin and the electromedical stimulator as ordered by a physician.

Device Dimensions



Sterilization Methods: 25kGy Gamma Radiation

For predicate device comparison performance comparison was based on the following properties.

1. Measurement of conductivity of the total electrode circuit from wire connector to the hydrogel
2. The strength of the electrode wire and the integrity of wire attachment.
3. The type of materials used in each of the electrode components.
4. The thickness of the hydrogel
5. Leadwire connector
6. Labeling information

Properties or Performance Characteristics	Target Sterile Electrode	Surgi-Stim Sterile Electrode	Reason for Substantial Equivalence
Electrode Backing Material	Non-woven	Non-woven	Using the same type of material
Method of attaching wire to electrode	Polyester Circular Disk	Polyester Circular Disk	Using similar strain relief made of the same material
Release liner card the electrode is stored on	Silicone Coated Paper	Silicone Coated Paper	Using the same type of material
Conductive Electrode Element	2 Mil Vinyl With Carbon Loaded Pigment Coated With Silver / Silver chloride Ink	2 Mil Vinyl With Carbon Loaded Pigment Coated With Silver / Silver chloride Ink	Using the same type of material
Hydrogel	Comfort Gel A (Promeon RG 63B Formulation) Thickness .032	Promeon RG 63B Formulation Thickness .032"	The Comfort Gel A and the RG 63B formulation are almost identical
Electrode Leadwire	Leadwire connector .080" or .059"	Leadwire connector .080" or .059"	Using the same type of connector
Labeling	Sterile for Single Patient Use	Sterile for Single Patient Use	Descriptive wording very similar
Labeling	States Potential Adverse Reactions is Skin Irritation	States Potential Adverse Reactions is Skin Irritation	Descriptive wording very similar
Electrode Impedance @ 1000 Hertz	Less Than 100 Ohms	Less Than 100 Ohms	Similar conductive properties
Force Required to Remove Wire From Electrode	More Than 6 Pounds of Force	More The 5 Pounds of Force	Exceeds Surgi-Stim Electrode

Indications for Use:
The sterile Target electrode is intended for use in Electrical Neuromuscular and Transcutaneous Electrical Nerve Stimulation.

Comparison to Predicate:
This device is substantially equivalent to its predicate device, the Surgi-Stim sterile electrodes. They provide similar indications for use and are all derived from similar materials, except the hydrogel.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 24 2008

Vision Quest Industries, Inc.
c/o Ms. Jaime Pulley
18011 Mitchell South
Irvine, CA 92614

Re: K072799
Trade/Device Name: Target Sterile Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: April 18, 2008
Received: April 22, 2008

Dear Ms. Pulley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: TARGET STERILE ELECTRODE

Indications for Use:

Sterile - Single Patient Use Only - Disposable

The sterile Target electrode is intended for use in Electrical Neuromuscular and Transcutaneous Electrical Nerve Stimulation.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for nkm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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